

Remarks

Applicant have carefully reviewed and considered the Office Action mailed on November 11, 2002. Claims 63, 64, 70, 72-74, 81, 84, 91, 98, 101, 103, 104, 111, 112, 119, and 125-128 are amended; claims 122-124 are canceled, and claim 129 is added; as a result, claims 63-108, 111-112, and 117-121, and 125-129 are now pending in this application. Also included in the amended claims are corrected readily apparent typographic errors. No new subject matter is added.

The following paragraphs correspond to those of the official action.

1. Claims 122-125 set forth in the amendment of Sept 4, 2002, have been canceled. Claims 125-128 (corresponding to claims filed as 122-125) were amended and renumbered as suggested by the Examiner. Applicant thank the Examiner for bringing this matter to Applicant's attention. The objection is believed to be overcome.
2. The amendment filed September 4, 2002 was objected to under 35 U.S.C. 132 for the reasons set forth in the office action. Applicant has amended the specification as indicated above to remove the objectionable "incorporation by reference" paragraph. The objection is believed to be overcome.

Rejections under 35 U.S.C. §112

3. Claim 119 was rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make, and/or use the invention. Applicant has amended claim 119 to delete the term "artificial organ" as suggested by the Examiner.
4. Claims 122-124 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which

Applicants regard as the invention. In order to expedite prosecution, Applicant has canceled claims 122-124.

5. Claims 125-128 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is respectfully traversed.

Applicant has amended claim 125 as indicated to recite “cyclic-flex fatigue resistance of 295 million cycles” and added claim 129 to recite “cyclic-flex fatigue resistance of 343 million cycles”. These claims are supported in the application as filed on page 26, lines 13-15.

In order to expedite prosecution, Applicant has amended claims 126 to 128 to delete “about” as required by the Examiner.

The Examiner questioned the meaning and basis of “degradation resistance ranking.”

Applicant respectfully submits that the term “degradation resistance” is readily evident to one of ordinary skill in the art upon review of Example 13, which describes the evaluation method and measurement in detail. In Example 13, the specimens tested and were rated according to the level of degradation. The rating scale, 0 (zero) for no visible degradation to 50 for fractured (torn) or degraded in all test images, is provided in the specification at page 25, lines 6-12.

Thus, Applicant respectfully submits that the term “degradation resistance” and its use as a qualitative term for “ranking” the relative performance of bio-materials is properly supported by the specification as filed.

6. Claims 126-128 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. This rejection is respectfully traversed.

The Examiner questioned 1) how to interpret “degradation resistance ranking” as a definitive limitation, and 2) the basis for the ranking having a definitive meaning. Applicant’s remarks in paragraph 5 above are also applicable here. Accordingly, Applicant respectfully submits that the language “degradation resistance ranking” and relative values presented in claims 126-128 are directed to one of ordinary skill in the art and particularly point out and distinctly claim Applicant’s invention.

7. Claims 81-103 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is respectfully traversed.

The Examiner indicated that adequate support was not provided in the specification for claiming polyurethanes molecular weights as “number average” molecular weights. Applicant respectfully submits that the application is directed to one of ordinary skill in the art and that one of ordinary skill in the art recognizes “number average” as the metric of choice in describing polyurethane formulations and would further recognize that measures of molecular weight of polyurethanes other than number average are not useful in calculating polyurethane formulations. Applicant respectfully submits herewith an excerpt from the treatise “Polyurethane Elastomer Chemistry” which supports the use of “number average molecular weight” as a preferred way to describe the recited polyurethane-urea elastomeric compositions of claims 81-103. (See page 44, last paragraph and age 43, last paragraph. A copy of this excerpt is enclosed for the Examiner’s convenience)

In addition, Applicant directs the Examiner’s attention to page 15, lines 9-14, of the specification. Here the text refers to a polymer prepared using poly(hexamethylene oxide) prepared according to U.S. Patent No. 5,403,912. The specification states that the poly(hexamethylene oxide) was prepared “as described by Gunatillake et al. and U.S. Patents 5,403,912”. In the '912 patent the poly(hexamethylene oxide) is reported in terms of M_n , number average

molecular weight, and determined by size exclusion chromatography (SEC). See for example, Example 1 of the '912 patent he. Thus, when reading the claims it would be readily apparent to the skilled artisan, upon review of the specification and the documents cited therein, that the number average molecular weight is the proper way to determine the molecular weight of the products.

8. Claims 63-103 and 117-128 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The rejection is respectfully traversed.

As indicated above Applicant has amended claim 63 to recite that the soft segment comprises “a macrodiamine compound of formula (I) and a macrodiol” and that the hard segment comprises “(ii) a chain extender comprising the diamine compound of formula (I).” Use of the “macrodiamine and macrodiol” in the soft segment and use of the “diamine” in the hard segment as chain extender is believed to distinguish by name, disposition in the polymer segments (hard v. soft), the two different segments of the polymer. The amine compounds of formula (I) are also distinguished in dependent claims and as disclosed in the application as filed, for example, claim 64 (diamine, see page 3, lines 20-23) and claim 81 (macrodiamine, see page 3, lines 20-23).

9. Claim 95 was rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The rejection is respectfully traversed.

The Examiner asserts that the language “macrodiamine compound of formula (I)”, lacked antecedent basis. Applicant has amended claim 84 (from which claim 95 depends) to include “macrodiamine compound of formula (I)”. Accordingly, amended claim is believed to be definite in its present form.

10. Claims 63-108, 111, 112, and 117-128 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The rejection is respectfully traversed.

Regarding the definition of R_5 and R_6 , the claims (63, 104, 111 and 112) have been amended to remove the erroneous recitation of “hydrogen” for R_5 and R_6 . Support for the amendment is contained in the specification as filed on page 4, line 16-19.

Regarding appropriate reactants in polyurethane-urea claims, claims 104 and 112 have been amended as indicated to recite a first chain extender diamine compound of formula (I) and a second chain extender selected from a group which includes diol chain extenders. Thus, the recited combinations of a soft segment having a macrodiol, and a hard segment having a diisocyanate, a first chain extender of formula (I), and a second chain extender, are believed to be definite to one of ordinary skill in the art and particularly point out and distinctly recite Applicant's invention.

Accordingly, withdrawal of all the above 35 U.S.C. § 112, rejections are respectfully requested.

Rejection under 35 U.S.C §103

Claims 63-108, 111, 112, and 117-128 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Szycher et al. U.S. 5,863,627 (Szycher '627) or WO 98/13405 or JP 4-248826, each in view of Li et al. U.S. 5,221,724 (Li '724) and Ohtaki et al. U.S. 5,861,085 (Ohtaki '085). This rejection is respectfully traversed.

13. The Examiner conceded that the primary documents (Szycher '627, WO 98/13405, and JP 4-248826) do “[not] disclose the specific use of an amine functional siloxane as a chain extender” (Official Action, page 6) as in the present invention. The Examiner asserts that Li

'724 discloses the use of compounds of formula (I) in biocompatible polyureas and polyurethane-ureas.

The Examiner also asserts that Ohtaki discloses amino functional tetraoganodisiloxanes as reactants with polyurethanes.

14. The Examiner concluded that since the amine functional polysiloxanes were known reactants for polyurethane-ureas and since they were known to bestow improved properties, it would have been obvious to use them as reactants within the compositions of the primary documents to obtain the present invention.

15. Applicant's claim amendments distinguish the soft and hard segments and as discussed above. The secondary documents do not teach the desirability of incorporating the diamine compounds of formula (I) into a hard segment, alone or in combination with the macrodiamine compounds of formula (I) and a macrodiol in the soft segment, of the recited polymers.

None of the cited documents {Szycher '627, WO 98/13405, or JP 4-248826; each in view of Li '724 and Ohtaki '085}, alone or in combination, disclose or suggest all of the elements of the presently claimed invention. Specifically, none of these documents disclose or suggest the use of a diamine compound of formula (I) as a chain extender in the hard segment as in compositions of the present invention. Additionally, none of these documents disclose or suggest polyurethane-urea compositions where the soft segment contains a silicone containing macrodiamine and macrodiol compound of formula (I) and a silicone containing diamine in the hard segment as in the present invention. Thus, because none of these documents, alone or in combination, provide all of the elements of the claimed invention they cannot provide the motivation to combine or provide any reasonable expectation of success in arriving at the present invention.

• **AMENDMENT AND RESPONSE TO OFFICE ACTION**

Serial Number: 09/933,938

Filing Date: August 21, 2001

Title: SILOXANE-CONTAINING POLYURETHANE-UREA COMPOSITIONS

Page 23

Dkt: 1207.008US1

Li does not cure the deficiencies of any of the primary documents to permit one to arrive at the claimed compositions. In contrast, Li discloses soft segments formed from a diisocyanate and an amine functional siloxane, and hard segments formed from chain extended diisocyanates using alkyl- or aryl-diols, or alkyl- or aryl-diamines as chain extenders.

Similarly, the Ohtaki disclosure of an amino functional tetraorganodisiloxane as a modifier for synthetic resins also does not cure or complete the deficiency of any of the primary documents to permit one to arrive at the claimed compositions.

Thus, it is respectfully submitted that the claimed invention is not obvious over the cited documents in an combination. Accordingly, Applicant respectfully request withdrawal of the rejection of the present claims under 35 U.S.C. § 103(a).

AMENDMENT AND RESPONSE TO OFFICE ACTION

Serial Number: 09/933,938

Filing Date: August 21, 2001

Title: SILOXANE-CONTAINING POLYURETHANE-UREA COMPOSITIONS

Page 24

Dkt: 1207.008US1

Conclusion

Applicant respectfully submit that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicants' attorney ((612) 359-3270) to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

PATHIRAJA A. GUNATILLAKE ET AL.

By their Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER &
KLUTH, P.A.

P.O. Box 2938
Minneapolis, MN 55402
(612) 359-3270

Date March 20, 2003 By William F. Prout
William F. Prout, Ph.D.
Reg. No. 33,995

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Commissioner of Patents, Washington, D.C. 20231, on this 20th day of March, 2003.

Danica A. DeHman
Name

[Signature]
Signature